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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,551	04/27/2006	Edward Fey	50047/015002	5268

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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

NOTIFICATION DATE	DELIVERY MODE
12/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/559,551	FEY ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-56* is/are pending in the application.

4a) Of the above claim(s) *6-10 and 12-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/16/2007;01/09/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Claims 1, 3-5 and 11 and of the following combination of ingredients: quercetin, vitamin B5, oat straw (*Avena sativa*), oat straw (*Avena sativa*) powder, L-methionine, bromelain, horsetail (*Equisetum spp*) and borage oil (*Borago officianalis*) in the reply filed on 09/17/2008 is acknowledged. Please note that the composition of claim 12 contains the non-elected specie "borage oil powder" and is thus not examined.

Claims 6-10 and 12-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/17/2008.

Claims 1, 3-5 and 11 are currently under examination.

Specification

The abstract of the disclosure is objected to for the following reasons: The abstract recites, "The present invention" in line 1. It is suggested that the term "present invention" be deleted from the language of the abstract. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered novel. Thus, the incorporation

of "present invention" into the language of the abstract is not appropriate. Appropriate correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 12 are rendered uncertain by the phrase "wherein the composition increases the endogenous expression of lubricin by at least 10% relative to an untreated control" because it is unclear as to what an "untreated control" is. Is Applicant referring to *in vitro* cell studies or to humans or to dogs, etc.? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurent et al. (A, US Patent number: 4,847,085), in view of Wadsworth et al. (B, US PreGrant Publication Number: 2002/0182276 A1), Watson (C, US Patent Number: 6,228,367) and Maurer et al. (N, EP 1208849).

Laurent teaches a composition for treatment and prevention of bone disorders, wherein the bone disorder is osteoarthritis, wherein the composition comprises oats, which is synonymous with oat straw (*Avena sativa*), D-L-methionine and panthothenate (which is synonymous with vitamin B_5).

Although Laurent does not teach that the composition increases endogenous expression of lubricin by at least 10% relative to an untreated control, the claimed functional properties are intrinsic to the preparation taught by Laurent because the ingredients and the route of administration for the delivery of the ingredients taught by Laurent are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a composition for treating osteoarthritis adapted for oral

administration, wherein said composition comprises at least two substances selected from: oat straw (*Avena sativa*), D-L-methionine and panthothenate (which is synonymous with vitamin B_5) taught by Laurent, intrinsically increase the endogenous expression of lubricin by at least 10% relative to an untreated control.

Laurent does not teach horsetail, oat straw powder or quercetin. However, Wadsworth teaches a composition comprising Noni, which contains methionine (See paragraph 0041), panthothenic acid (which is synonymous with vitamin B_5), horsetail herb (See paragraph 0038), oatmeal (which reads on oat straw powder, See paragraph 0061) and quercetin (See paragraph 0095) and wherein the composition can treat arthritis (See paragraph 0048).

Laurent does not teach borage seed oil. However, Watson teaches a food supplement comprising borage seed oil for improving joint flexibility.

Laurent does not teach bromelain. However, Maurer teaches a composition for treating rheumatoid arthritis or polyarthritis comprising bromelain.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition taught by Laurent by combining oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain, which are all ingredients that have the same functional effect of treating arthritis and improving joints. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients of oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain for their

known benefit in treating arthritis and improving joints since each claimed ingredient is well known in the art for the same purpose, as useful for treating arthritis and improving joints and for the following reason:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain, are useful for treating arthritis and improving joints, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective for treating arthritis and improving joints. Thus, combining them flows logically from their having been individually taught in prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to combine oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain to provide a beneficial composition for the expected benefit of treating arthritis and improving joints because at the time the invention was made, the instantly

claimed ingredients of oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain were known to be useful for treating arthritis and improving joints, and since the ingredients and mode of administering the ingredients, which are one and the same as those claimed by Applicants, was known in the art at the time the invention was made. Thus the combined composition of oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain would have been expected to be even more effective for treating arthritis and improving joints because the claimed ingredients were all useful for this purpose, as clearly taught by the above references.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following ingredients for treating arthritis and improving joints to gain the benefits of individual components as part of a composition for treating arthritis and improving joints: oat straw (*Avena sativa*), D-L-methionine, vitamin B_5, horsetail, oat straw powder, quercetin, borage seed oil and bromelain, to provide a beneficial composition for the expected benefit of treating arthritis and improving joints because at the time the invention was made, these ingredients were well known treating arthritis and improving joints.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary

skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
December 1, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655